

JMM:CPK  
F. #2013R01480

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA

- against -

MICHAEL SETTINERI,

Defendant.

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THE UNITED STATES ATTORNEY CHARGES:

INTRODUCTION

At all times relevant to this Information:

1. The United States Food and Drug Administration ("FDA") was an agency of the United States government responsible for enforcing the provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. The FDA's responsibilities included, among other things, regulating drugs shipped, delivered and received in interstate commerce.
2. The FDCA prohibited the introduction or delivery for introduction into interstate commerce, or the causing thereof, of a drug that was misbranded. 21 U.S.C. § 331(a).
3. The FDCA defined the term "drug" to mean, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(g)(1).

INFORMATION

**C R - 15 330**

Cr. No. (T. 21, U.S.C., §§ 331(a), 333(a)(2) and 352(a); T. 18, U.S.C., §§ 2 and 3551 et seq.)

**BIANCO, J.  
LINDSAY, M.**

4. A drug was deemed to be misbranded under the FDCA if it was an unapproved new drug. 21 U.S.C. § 352(a).

5. The defendant MICHAEL SETTINERI operated a business he called Infinitan through the website [www.buymelanotanii2.com](http://www.buymelanotanii2.com) from his residence in Coram, New York.

6. Infinitan, through the defendant MICHAEL SETTINERI, trafficked in the drug Melanotan II, a drug which purported to alter the pigmentation of skin and was not approved by the FDA for sale in the United States.

7. Melanotan II, an unapproved drug, which claimed to be an article (other than food) intended to affect the structure or any function of the body of man or other animals, was a misbranded drug within the meaning of 21 U.S.C. § 352(a).

8. On or about and between December 1, 2010 and August 1, 2013, Melanotan II was introduced into interstate commerce to customers located across the United States and in foreign countries by the defendant MICHAEL SETTINERI, who realized proceeds totaling thousands of dollars from the sale of the product.


COUNT ONE

(Introduction of Misbranded Drugs into Interstate Commerce)

9. The allegations contained in paragraphs one through eight of this Information are realleged and incorporated as if fully set forth in this paragraph.

10. On or about July 23, 2013, within the Eastern District of New York and elsewhere, the defendant MICHAEL SETTINERI, together with others, did knowingly and intentionally introduce and cause to be introduced into interstate commerce, with the intent to defraud and mislead, drugs, to wit: Melanotan II, which was misbranded.

(Title 18, United States Code, Sections 2 and 3551 et seq.; Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(a))

  
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